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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/848,377	05/03/2001	Gregory Prince	469201-540	8081
7590 08/10/2005 CARELLA, BYRNE, BAIN, GILFILLAN, CECCHI, STEWART & OLSTEIN 6 Becker Farm Road Roseland, NJ 07068			EXAMINER HILL, MYRON G	
			ART UNIT 1648	PAPER NUMBER

DATE MAILED: 08/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/848,377

**Applicant(s)**

PRINCE ET AL.

**Examiner**

Myron G. Hill

**Art Unit**

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 14 September 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) 1-21 and 25-27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 22-4, 28-40 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

The examiner of your application has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1648, Examiner Hill.

This action is in response to the paper filed 9 September 2004.

Applicant's argument's concerning claim 28 are acknowledged and claim 28 is rejoined.

This action is on claims 22-24 and 28-40.

### ***Rejections Withdrawn***

#### ***Claim Rejections - 35 USC § 102***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim 24 was rejected under 35 U.S.C. 102(b) as being anticipated by Johnson et al.

Applicant's statements of fact and arguments are persuasive and the rejection is withdrawn.

Claims 22, 23, 29-34, 36-40 were rejected under 35 U.S.C. 102(b) as being anticipated by Prince et al. (US PAT 5290540).

Applicant has amended the claims and the rejection is withdrawn.

***Claim Rejections - 35 USC § 103***

Claim 35 was rejected under 35 U.S.C. 103(a) as being unpatentable over Prince *et al.* (US PAT 5290540) in view of Johnson *et al.* (JID, *supra*).

Johnson *et al.* is not available as prior art and the rejection is withdrawn.

***New Rejections Necessitated By Amendment***

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 22-4 and 28-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Prince *et al.* (US PAT 5290540, 1 March 1994 issue date) and Johnson *et al.* (USPAT 5824307, October 20, 1998 issue date).

The claims are drawn to a method of treating RSV with a combination treatment of antiviral antibody and anti-inflammatory agent.

Prince *et al.* was discussed in the previous action and teaches antiviral antibody and anti-inflammatory agent combination treatment of RSV infection. Prince *et al.* also teach antibodies to bacterium to be used in therapy (column 5, line 60 to column 6, line 5).

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Prince *et al.* do not teach systemic administration of anti-infectious agent antibody or MEDI-493.

Johnson *et al.* teach an antibody (claim 1) that appears to be the same as MEDI-493 because it is a mouse murine mAb that has been humanized and is ant-RSV F and that the prior art teaches systemic delivery of RSVIG (containing anti-RSV antibodies) (column 1, 33-35). One of ordinary skill in the art at the time of invention would have been motivated to use the antibodies of Johnson *et al.* in the combination of Prince *et al.* to treat RSV because Johnson *et al.* teaches that these antibodies are useful for therapy and more neutralizing than the starting murine mAbs. One of ordinary skill in the art at the time of invention would have known that antibodies could be administered systemically with the expectation of success (column 1, lines 33-35). The use specific recombinant antibodies avoids the limitations as taught in Johnson *et al.* that RSVIG therapy has the disadvantages of large volumes and venous access, and regular hospital visits (column 1, lines 37-48). The use of the antibodies of Johnson *et al.* avoids the limitations by being higher titer (antiRSV and antibodies per ml) and thus requires less antibody to be delivered and because it is a humanized recombinant antibody, it would not raise an inappropriate immune response to the antibody itself. The dose range can be determined by one of ordinary skill in the art using the ranges taught in Prince *et al.* as a starting point. One of ordinary skill in the art would have been motivated to use a combination antibodies to infectious agents to treat respiratory conditions because it is known that multiple organisms can cause respiratory problems. One of ordinary skill in the art would have had the expectation of success in using a

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combination treatment of microorganisms each are known to work independently and one would expect at least an additive effect.

Thus, it would be *prima face* obvious to modify the method of Prince *et al.* to use the antibody of Johnson *et al.* and give the antibody systemically with the expectation of success because the individual parts of therapy has been shown to work previously.

### **Conclusion**

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

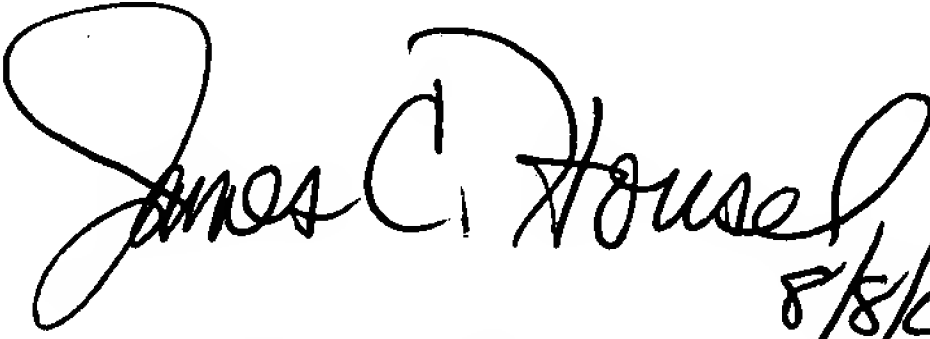
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Myron G. Hill whose telephone number is 571-272-0901. The examiner can normally be reached on 8:30 am-5 pm Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MGH  
8/4/05

  
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8/8/05